



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of the Assistant Secretary for
Preparedness and Response (ASPR)

PAHPA Stakeholders Meeting

Biomedical Advanced Research and Development Authority (BARDA)

**November 8, 2007
Washington, D.C.**



Outline

- **Overview**
 - **Key Program Areas**
 - **Statutory Requirements**
- **Major Accomplishments to Date**
- **Next Steps**
- **Discussion and Q and A**



BARDA Responsibilities

- Coordinate an integrated, systematic approach to planning for and executing research, development and acquisition of medical countermeasures for public health emergencies
- Support the ASPR in leading the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE)
- Drive medical countermeasure analysis and prioritization
 - *HHS PHEMCE Strategy for CBRN Threats*
 - *HHS PHEMCE Implementation Plan for CBRN Threats*
- Execute advanced development and procurement of medical countermeasures for CBRN threats and pandemic influenza
 - Advanced development under BARDA
 - Acquisition under Project BioShield (CBRN material threats)
 - Acquisition with direct appropriations for pandemic influenza



Overview: Statutory Requirements

Title IV: Pandemic and Biodefense Vaccine and Drug Development

- Establishes the Biomedical Advanced Research and Development Authority (BARDA)
 - Facilitate collaboration among USG, industry, and academia
 - Support the advanced research and development of MCMs
 - Promote innovation to reduce time and cost of MCM
- Establishes the Biodefense MCM Development Fund (Advanced Development)
 - Fund development of products across so-called “Valley of Death”
 - Authorizes (not appropriated) \$1.07 billion for FY2006-2008
 - ◆ Reflects existing commitments in biodefense and pandemic flu initiatives
 - Separate from the preexisting BioShield Special Reserve Fund
- Makes reforms to BioShield procurement program / New Authorities
 - Advanced Payments
 - Milestone Payments
 - Anti-trust Exemption



Overview: Statutory Requirements

Title IV: Pandemic and Biodefense Vaccine and Drug Development (continued)

- **Strategic Plan for Medical Countermeasure Research, Development, and Procurement**
- **Technology Demonstrations**
- **Personnel Authorities**
- **National Biodefense Science Board**
- **FDA to provide technical assistance to developers on manufacturing and regulatory processes if the Secretary determines that a shortage or potential shortage of a critical countermeasure may occur**



Public Health Emergency Medical Countermeasures Enterprise (PHEMCE)

- Serves as the mechanism for implementation of the medical countermeasures mission
- Addresses both naturally occurring and deliberately induced public health events
- More fully integrates the Strategic National Stockpile (SNS), BioShield, and Influenza missions
- Expands beyond the scope and range (\$5.6B; FY04-13) of the Project BioShield Act of 2004
- Encompasses medical countermeasure issues along the full spectrum of the Enterprise





Strategic Planning & Policy Milestones

PUBLIC LAW 109-417—DEC. 19, 2006 120 STAT. 2881

THE WHITE HOUSE
PRESIDENT
GEORGE W. BUSH

Federal Register / Vol. 72, No. 53 / Tuesday, March 20, 2007 / Notices 13169

Homeland

January 31,

Subject: Me

BACKGROUND

(1) Weapons (CBRN) — it challenges if compromise damage that

(2) Our Nat for the 21st ability to ma but we must have made a mitigate imp and acquit from CBRN

(3) It is not possible this caused by e process. TN to Combat V Nation's me

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(b) Y evolv

Federal Register / Vol. 72, No. 77 / Monday, April 23, 2007 / Notices 20117

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the National Vaccine Advisory Committee

AGENCY: Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response (ASPR)

SUMMARY: Biomedical Advanced Research and Development Authority (BARDA) Office of the Assistant Secretary for Preparedness and Response (ASPR) U.S. Department of Health and Human Services (HHS)

Draft BARDA Strategic Plan for Medical Countermeasure Research, Development, and Procurement

July 2007

DEPARTMENT OF HEALTH & HUMAN SERVICES-USA

Sept 2006: HHS releases the Draft **Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategy for Chemical, Biological, Radiological and Nuclear Threats** and first BioShield Stakeholders Workshop convened

19 Dec 2006: Enactment of the **Pandemic and All-Hazards Preparedness Act**

31 Jan 2007: President Bush Signs HSPD-18 **Medical Countermeasures against Weapons of Mass Destruction**

20 Mar 2007: HHS releases the **PHEMCE Strategy for Chemical, Biological, Radiological and Nuclear Threats**

23 Apr 2007: HHS releases the **PHEMCE Implementation Plan for Chemical, Biological, Radiological and Nuclear (CBRN) Threats**

6 July 2007: HHS releases the Draft **BARDA Strategic Plan for Medical Countermeasure Research, Development and Procurement**



Projected Acquisitions for Top-Priority MCMs

Near-Term (FY 2007-08)
Funding Source & Level

Mid-Term (FY 2009-13)
Funding Source & Level

Medical Countermeasures (MCMs) for Biological Threats

Diagnostics		SRF ≤ \$100 M
Broad spectrum antibiotic(s)	DSNS ≤ \$100 M	DSNS ≤ \$100 M SRF > \$100 M
Anthrax antitoxin(s)		SRF > \$100 M
Anthrax vaccine(s)	SRF > \$100 M	
Filovirus MCMs		SRF > \$100 M
Smallpox antiviral		SRF ≤ \$100 M
Smallpox vaccine	SRF > \$100 M	

Medical Countermeasures for Radiological and Nuclear Threats

ARS/DEARE	SRF > \$100 M	SRF > \$100 M
Biodosimetry, Bioassay		SRF ≤ \$100 M
Radionuclide-specific agent(s)		SRF ≤ \$100 M

Medical Countermeasures for Chemical Threats

Enterprise CHEMPACKs		DSNS > \$100 M
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CBRN Funding Activities

Medical Countermeasure Procurements for the Strategic National Stockpile	<ul style="list-style-type: none">• Anthrax:<ul style="list-style-type: none">▪ Anthrax Vaccine Adsorbed▪ ABthrax Monoclonal Antibody▪ Anthrax Immune Globulin• Rad/Nuc<ul style="list-style-type: none">▪ Pediatric Formulation of KI▪ Ca-DTPA and Zn-DTPA• Smallpox<ul style="list-style-type: none">▪ Next-generation smallpox vaccine – modified vaccinia Ankara (MVA)• Botulism<ul style="list-style-type: none">▪ Heptavalent Botulinum Antitoxin
Sources Sought	<ul style="list-style-type: none">• rPA Anthrax Vaccine• Medical Countermeasures to mitigate and/or treat acute radiation syndrome
Advanced Development (Contracts Awarded)	<ul style="list-style-type: none">• Plague and tularemia antibiotic development• Anthrax immune globulin development• Anthrax antitoxin development (2 Contracts)
Advanced Development BAA	<ul style="list-style-type: none">• Advanced Development of Multivalent Filovirus (Ebola and Marburg) Hemorrhagic Fever Vaccines



HHS Pandemic Influenza Preparedness: Medical Countermeasures Summary

- **Robust and comprehensive portfolio approach to developing and acquiring a broad array of medical countermeasures (vaccines, antivirals, and diagnostics)**
 - HHS has initiated and/or awarded contracts for all of the Phase 1 medical countermeasure programs within one year of the initial appropriation in December 2005
 - ◆ Currently 25 contracts with obligations over \$3 billion
 - Initiated Phase 2 initiatives for vaccine infrastructure building (2 awards in June 2007) and management of vaccine and antiviral stockpiles
- **Cooperative effort leveraging resources from throughout HHS (NIH, CDC, FDA & ASPR) and Industry**



HHS Pandemic Influenza Preparedness: Medical Countermeasures Portfolio

	Vaccines	Antivirals	Diagnostics
<i>Advanced Development</i>	Cell-based Antigen-sparing Next Generation Egg-based Supply	Peramivir	Rapid Diagnostics Point-of-Care
Stockpile Acquisitions	H5N1 Vaccine Stockpiles	Tamiflu® & Relenza® Federal Stockpiles State Stockpiles	
Infrastructure Building	Retrofit Existing Mfg Facilities Build New Cell-based Mfg Facilities		



U.S. Pan Flu MCM Strategic Goals: Current and Future

- **Vaccines**

- **Goal #1:** Establish and maintain a dynamic pre-pandemic influenza vaccine stockpile available for 20 M persons (2 doses/person) or more persons depending on vaccine mfg. capacity & results of dose-sparing adjuvant studies and prime-boost immunization studies: H5N1 stockpiles
- **Goal #2:** Provide pandemic vaccine to all U.S. citizens within 6 months of a pandemic declaration: pandemic vaccine (600 M doses)

- **Antivirals**

- **Goal #1:** Provide influenza antiviral drug stockpiles for pandemic treatment of 25% of U.S. population (75 M treatment courses) and antivirals for prophylactic usage as a community mitigation measure
- **Goal #2:** Provide influenza antiviral drug stockpiles for strategic limited containment at onset of pandemic (6 M treatment courses)



U.S. Pan Flu MCM Strategic Goals: Current and Future continued

- **Diagnostics**
 - **Goal #1: Develop new high-throughput laboratory & point-of-care (POC) influenza diagnostics for pandemic virus detection**
- **Other Countermeasures**
 - **Goal #1: Develop and acquire other MCMs including syringes/needles, masks/respirators, ventilators, antibiotics, & other supplies**

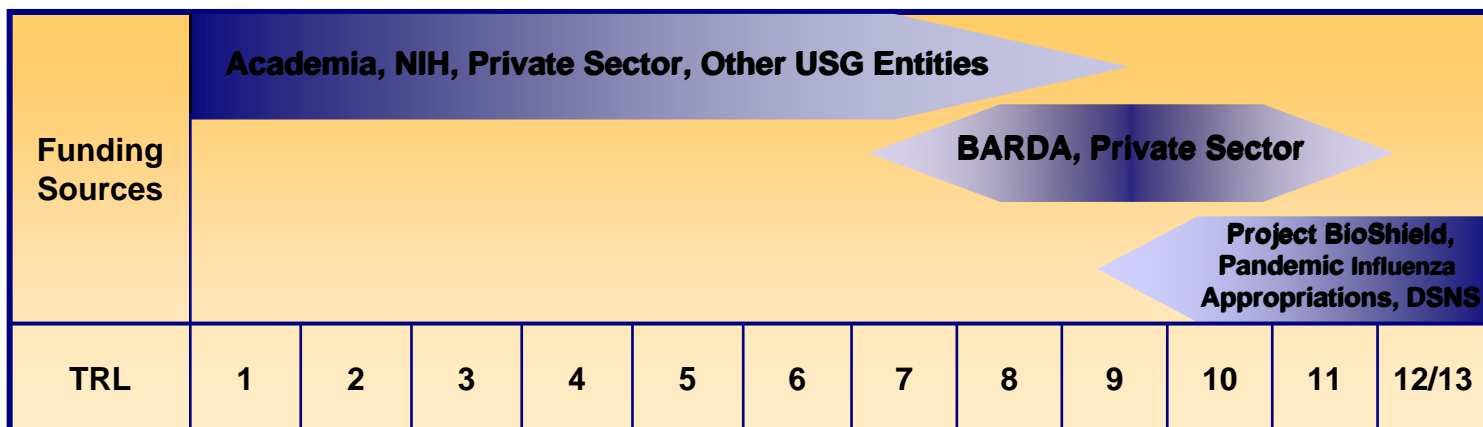
National Strategy for Pandemic Influenza (Nov 2005) and HHS Pandemic Influenza Plan (Nov 2005)

www.pandemicflu.gov



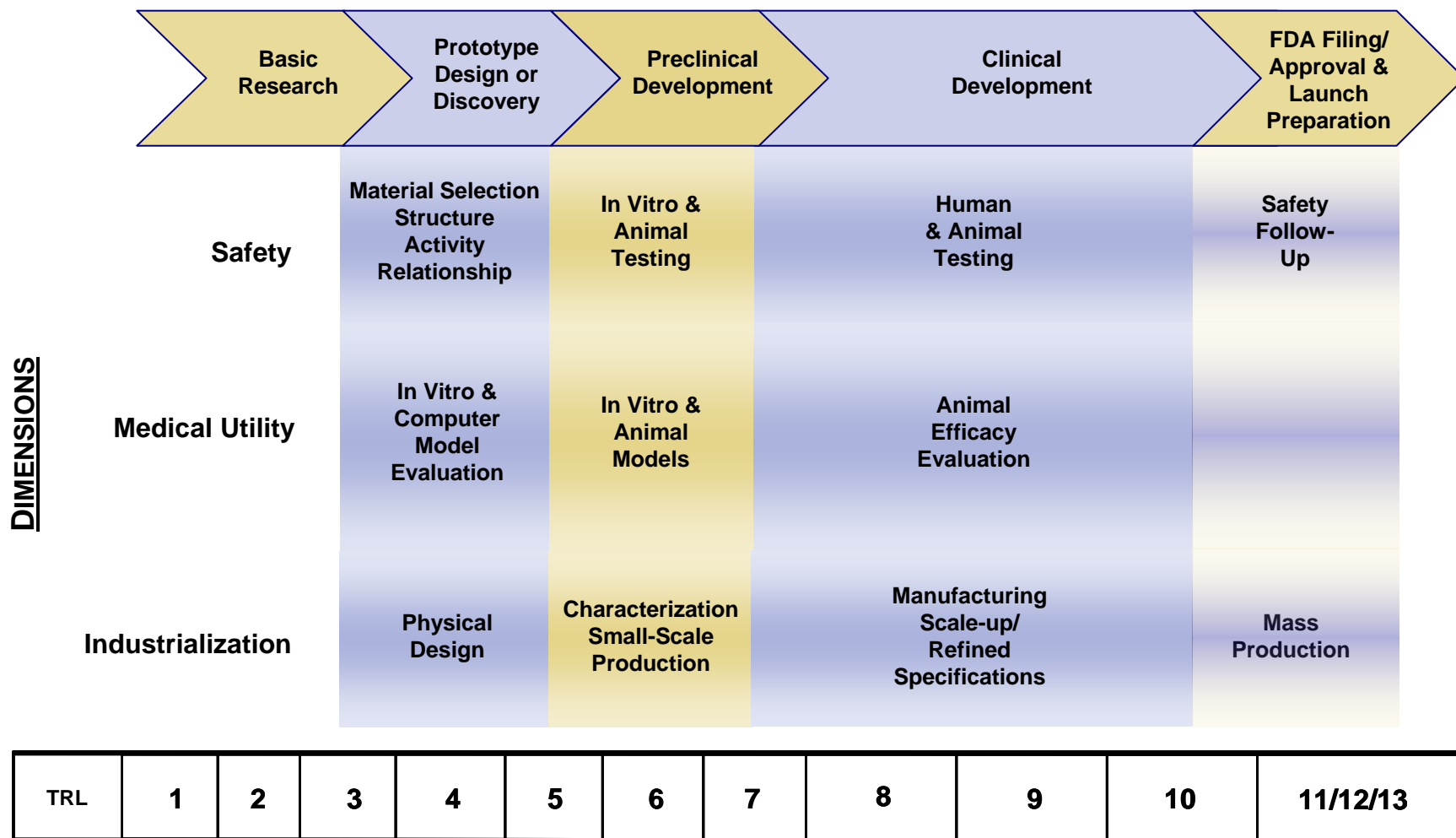
Draft BARDA Strategic Plan: Research → Development → Acquisition

- **Technology Readiness Levels:** Formalized decision points for the transition of technologies from early research to advanced R&D to procurement
 - Department of Defense (DoD) / National Institutes of Health (NIH)
- **Basic Research and Development (~TRL 1 through TRL 8)**
- **Advanced Research and Development (~TRL 7 through TRL 10)**
 - General Eligibility for BARDA funding support
- **Transition to Acquisition (~TRL 9 through TRL 12/13)**





Technology Readiness Levels



Adapted from the FDA Critical Path Report (March 2004)



National Biodefense Science Board (NBSB)

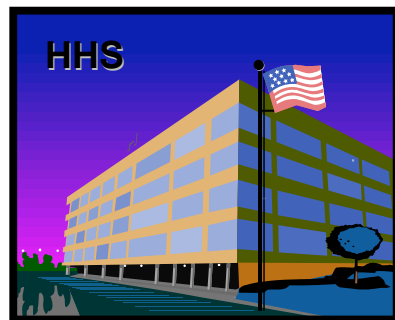
“Planning responses to incidents involving chemical, biological, nuclear or radiological agents requires state-of-the-art science. This new advisory board will add a wide range of expertise and viewpoints from outside of government to help inform HHS decision-making processes.”

*Secretary Michael O. Leavitt
U.S. Department of Health and Human Services
June 19, 2007*

- **Purpose: To provide expert advice and guidance to the Secretary on scientific, technical and other matters of special interest to HHS regarding activities to prevent, prepare for and respond to adverse health effects of public health emergencies resulting from chemical, biological, nuclear, and radiological events, whether naturally occurring, accidental, or deliberate.**
- Charter signed by Secretary Leavitt on May 24, 2007
- Federal Register notice published on June 20, 2007

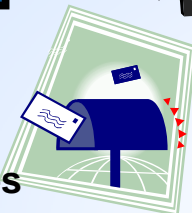


Stakeholder Engagement



HHS

RFIs
Sources
Sought Notices



Stakeholder Portal
MedicalCountermeasures.gov



Briefings



Federal Register
Notices/ Draft RFPs/
RFPs



PHEMC Enterprise Stakeholders
Workshop; BARDA Dialogues;
BARDA Industry Day



National
Biodefense
Science Board



External
Stakeholders





Next Steps

- **Appoint BARDA Director by the end of fall 2007**
- **Policies and guidelines for Project BioShield authorities under PAHPA**
 - **Advance payments**
 - **Waiver of the requirement to advertise contracts for supplies or services**
 - **Use of milestone payments under contracts, grants, cooperative agreements**
 - **Other transaction authority.**
- **Acquisitions outlined in the *PHEMCE Implementation Plan***
- **Version 2 of the *PHEMCE Implementation Plan* to be released in 2009**
- **Kick-off meeting of the NBSB on December 17-18, 2007**
- **Meeting management enhancements to MedicalCountermeasures.gov**
- **First biennial report to Congress on the use of BARDA personnel authorities to recruit, retain, and manage staff.**
- **Publish the final BARDA Strategic Plan for inclusion in the National Health Security Strategy**



Discussion

- ***BARDA:*** What are the biggest challenges to participating in BARDA programs? What would further facilitate broader participation?
- ***Project BioShield:*** What are the barriers to the development of a robust program?
- ***Stakeholder Outreach and Transparency:*** What are additional avenues HHS should pursue in reaching out to stakeholders? What do different stakeholder groups (industry, state and local governments, etc.) need from BARDA?
- ***Planning:*** Do the *PHEMCE Implementation Plan* and the *Draft BARDA Strategic Plan* effectively allow for private industry business planning?
- ***Innovation:*** How can BARDA promote and support innovation in medical countermeasure research and development?
- ***Risk:*** Is risk to the Federal government/private industry being appropriately shared and/or managed? If not, what is the appropriate balance and what actions by either HHS or private industry would achieve it?



Online Resources



BARDA:

URL: www.hhs.gov/aspr/barda/

E-Mail: BARDA@hhs.gov

- Upcoming Events
- Acquisitions
- BioShield
- Influenza Programs



MedicalCountermeasures.gov

- Federally-sponsored conferences
- Funding opportunities
- Resource programs
- Regulatory guidance
- Federal strategies and reports





Q and A

Thank You!

Contact Information:

BARDA.gov

www.hhs.gov/aspr/barda

www.medicalcountermeasures.gov